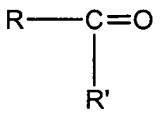
REMARKS

This amendment is submitted in response to the non-final Office Action mailed on November 18, 2004. Claims 1-25 are pending in this application. In the Office Action, Claims 1-2, 5, 16, 22 and 25 are rejected under 35 U.S.C. §102 and Claims 1, 5 and 14-25 are rejected under 35 U.S.C. §103. In response Claim 1 has been amended, and Claim 2 has been canceled. This amendment does not add new matter. In view of the amendments and/or for the response set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claims 1-2 and 5 are rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,618,955 to Mechoulam et al. ("*Mechoulam*"). Claims 1, 5, 16, 22 and 25 are rejected under 35 U.S.C. §102(b) as anticipated by WO 96/37200 to Stordy et al. ("*Stordy*"). Applicants respectfully disagree with and traverse these rejections for at least the reasons set forth below.

Claim 1 recites, in part, a composition for oral administration, comprising a naturally occurring precursor that is metabolised to a compound having anandamide activity for use as a medicament, wherein the precursor is a LCPUFA or derivative thereof of the general formula X:



wherein R is the alkenyl moiety of the LCPUFA of total chain length 16-28 carbon atoms with 2-6 double bonds, with the first double bond at the c-1, c-3 c6, c7, c9 c12 position, counting from the non carboxyl (methyl) part of the molecule; and where R" is selected from the group consisting of -H, lower alkyl, -OH, NH_3, $NHCH_2CH_2OH$, and an acid addition salt or complex thereof. *Mechoulam* is directed to polyunsaturated fatty acid amides and their derivatives, which are capable of mimicking naturally occurring anandamides in the brain and binding the cannabinoid receptor. See, *Mechoulam*, column 1, lines 20-60. The compounds exhibit physiological activity and are useful as active ingredients in pharmaceutical compositions for the treatment of several diseases. The polyunsaturated acids mentioned are merely specified in connection with the synthesis of the polyunsaturated fatty acid amides and their derivatives.

However, *Mechoulam* fails to disclose or suggest the presently claimed LCPUFA or derivatives thereof used as active compounds in a nutritional composition as required by the present claims. The Patent Office even admits same. See, Office Action, page 5.

Stordy is directed to a method for preparing a composition to be used for treating disorders such as dyslexia, inadequate night vision or dark adaption. These compounds are described as containing, among other things, DHA. See, *Stordy*, page 1. However, contrary to the Patent Office's assertions, independent Claims 1 and 16 do not even recite docosahexanoic acid. Further, *Stordy* also fails to disclose or suggest the presently claimed LCPUFA or derivatives thereof used as active compounds in a nutritional composition as required by the present claims.

For the reasons discussed above, Applicants respectfully submit that Claims 1 and 16 and Claims 5, 22 and 25 that depend from these claims are novel, nonobvious and distinguishable from the cited reference. Accordingly, Applicants respectfully request that the rejection of Claims 1-2, 5, 16, 22 and 25 under 35 U.S.C. §102(b) be withdrawn.

In the Office Action, Claims 1, 5 and 14-25 are rejected under 35 U.S.C. §103 as being unpatentable over *Mechoulam* in view of *Stordy* further in view of the combination of U.S. Patent No. 5,874,459 to Makriyannis et al. ("*Makriyannis*") in view of WO 94/28913 to Kyle et al. ("*Kyle*"). Applicants believe these rejections are improper and respectfully traverse them for at least the reasons set forth below.

The present claims pertain to the provision of an agent that is suitable for the treatment of a variety of different diseases without give rise to known side affects such as nausea or cramping. Additionally, the agent may be easily incorporated by an individual. Thus, the present invention provides naturally occurring precursors that are metabolized to a compound exhibiting anandamide activity. Surprisingly, Applicants have found that a composition containing such an agent may be useful for the treatment of a variety of diseases.

As discussed previously, *Mechoulam* and *Stordy* are deficient with respect to the presently claimed invention. For example, the derivatives specified in *Mechoulam* are derivatives of the polyunsaturated fatty acid amides and thus not identical to the polyunsaturated acids of the claimed invention. *Mechoulam* also fails to disclose or suggest that the

polyunsaturated acids used for the synthesis of the respective acid amides should be incorporated in a nutritional composition.

Stordy and *Kyle* both merely specify the use of non-modified polyunsaturated acids like DHA or ARA. They fail to disclose that the polyunsaturated acids have an additional residue or moiety as required, for example, by Claim 1. Further, *Kyle* is directed to a composition that is used for the treatment of disorders associated with deficiencies in highly unsaturated fatty acids such as DHA and ARA. *Kyle* fails to disclose or suggest derivatives of polyunsaturated acids being used as active compounds according to the claimed invention.

Makriyannis is directed to a method for inhibiting anandamide amidase in an individual or animal and novel inhibitors of anandamide amidase. *Makriyannis* fails to disclose or suggest derivatives of polyunsaturated acids being used as active compounds according to the claimed invention. In fact, *Makriyannis* relates to a completely different objective because the compounds specified therein are compounds capable of inhibiting the degradation of anandamide by inhibiting the enzyme anandamide amidase, which teaches away from the claimed invention. See, *Makriyannis*, column 3, lines 38-60. The present claims pertain to precursors that are metabolized to a compound exhibiting anadamide activity. This difference in mode of action explains the different chemical structures of the compounds used in *Makriyannis*. Consequently, there is no evidence that the composition in *Makriyannis* may successfully be used for the specific purpose of the claimed invention.

For the reasons discussed above, the combination of *Mechoulam* in view of *Stordy*, *Makriyannis* and *Kyle* does not teach, suggest, or even disclose the claimed invention, and thus, fails to render the claimed subject matter obvious for at least these reasons.

Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 1, 5 and 14-25 be reconsidered and the rejections be withdrawn.

Finally, the Patent Office has not provide support for an objection or rejection of Claims 3-4 and 6-13. Applicants respectfully submit that these claims are allowable for at least the reasons set forth above.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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